UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,522	11/20/2001	Jeffrey E. Stahmann	279.400US1	3079

21186 7590 07/15/2004

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	5

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,522	STAHMANN ET AL.	
	Examiner	Art Unit	
	Kristen Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/16/03 (IDS)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,11,13-18,26 and 28-32* is/are rejected.

7)☒ Claim(s) *4-10, 12, 19-25,27,33-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1- 3, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Vanderlinde et al. (2002/0082509).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Vanderlinde et al. shows a cardiac rhythm management device comprising a plurality of sensing channels comprising an electrode (24a-b) connected to a sense amplifier (21a-b); a plurality of pacing channels comprising an electrode (24a-b) connected to a pulse generator (22a-b); a controller (10) which is programmed to: pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy (arrhythmia) ([0013]).

With respect to claim 16, Vanderlinde et al. shows a method for operating a cardiac rhythm management device, comprising: sensing cardiac electrical activity via a plurality of sensing channels; outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode; and storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy (arrhythmia) ([0013]).

Regarding claims 2 and 17, Vanderlinde et al. shows the stored data is an electrogram from the selected sensing channel ([0013]).

With respect to claims 3 and 18, Vanderlinde et al. shows the stored data is marker/interval data reflecting sensing and pacing events in the selected sensing channel and time intervals therebetween (Figs. 2A-2D).

3. Claims 1, 13-14, 16, and 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Stahman et al. (6,480,742).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Stahman et al. shows a cardiac rhythm management device comprising a plurality of sensing channels comprising an electrode (24a-b, 34a-b) connected to a sense amplifier (21a-b, 31a-b); a plurality of pacing channels comprising an electrode (24a-b,

34a-b) connected to a pulse generator (22a-b, 32a-b); a controller (10) which is programmed to: pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy (Col. 2, lines 25-Col. 3, line 17; Col. 9, line 47-Col. 10, line 12).

With respect to claim 16, Stahman et al. shows a method for operating a cardiac rhythm management device, comprising: sensing cardiac electrical activity via a plurality of sensing channels; outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode; and storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy (Col. 2, lines 25-Col. 3, line 17; Col. 9, line 47-Col. 10, line 12).

Regarding claims 13, and 28, Stahman et al. shows the triggering condition is stored in a memory upon its detection (Col 2, lines 25-Col. 3, line 17).

With respect to claims 14, and 29, Stahman et al. shows statistical data regarding the triggering parameter is stored in a memory upon detection of a triggering condition (Figs 2-5).

4. Claims 1, 15-16, and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Kramer et al. (2003/0060851).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived

from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Kramer et al. shows a cardiac rhythm management device comprising a plurality of sensing channels comprising an electrode connected to a sense amplifier; a plurality of pacing channels comprising an electrode connected to a pulse generator; a controller (24) which is programmed to: pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy ([0042]; Fig. 7C).

With respect to claim 16, Kramer et al. shows a method for operating a cardiac rhythm management device, comprising: sensing cardiac electrical activity via a plurality of sensing channels; outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode; and storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy ([0042]; Fig. 7C).

Regarding claims 15, and 30, Kramer et al. shows additional data regarding the physical condition of a patient in whom the device is implanted is stored in a memory upon detection of a triggering condition. ([0037], and [0039] last sentence).

Regarding claims 31-32, Kramer et al. shows the data is stored for a specified storage time (132) upon detection of a triggering condition (Fig. 7C).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11 and 26 are rejected under 35 U.S.C. 103(a) as being obvious over Vanderlinde et al. (2002/0082509) in view of Peterson (5,447,519). Vanderlinde et al. is as explained before. Although Venderlinde et al. fails to teach the data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition is stored in a memory upon detection of the triggering condition, attention is directed to Peterson which teaches the storage of the time period preceding a triggering condition in order to aid in diagnosis (Col. 12, lines 58-62). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device and method of Vanderlinde et al. to store in memory upon the detection of the triggering condition, data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition as Peterson teaches in order to aid in diagnosis.

7. Claims 11 and 26 are rejected under 35 U.S.C. 103(a) as being obvious over Stahman et al. (6,480,742) in view of Peterson (5,447,519). Stahman et al. is as explained before. Although Stahman et al fails to teach the data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition is stored in a memory upon detection of the triggering condition, attention is directed to Peterson which teaches the storage of the time period preceding a triggering condition in order to aid in diagnosis (Col. 12,

lines 58-62). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device and method of Stahman et al. to store in memory upon the detection of the triggering condition, data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition as Peterson teaches in order to aid in diagnosis.

8. Claims 11 and 26 are rejected under 35 U.S.C. 103(a) as being obvious over Kramer et al. (2003/0060851) in view of Peterson (5,447,519). Kramer et al. is as explained before. Although Kramer et al. fails to teach the data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition is stored in a memory upon detection of the triggering condition, attention is directed to Peterson which teaches the storage of the time period preceding a triggering condition in order to aid in diagnosis (Col. 12, lines 58-62). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device and method of Kramer et al. to store in memory upon the detection of the triggering condition, data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition as Peterson teaches in order to aid in diagnosis.

The applied references have a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the references, it constitutes prior art only under 35 U.S.C. 102(e). These rejections under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which

corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Allowable Subject Matter

9. Claims 4-10, 12, 19-25, 27, and 33-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 4, and 19, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy, all in combination with the triggering condition being when the

percent of paced cycles over a specified period of time in either or both ventricles has dropped below a specified threshold value.

With respect to claims 5 and 20, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy, all in combination with the triggering condition being when the percent of paced cycles over a specified period of time in either or both ventricles has dropped below a specified threshold value within a particular rate range.

Regarding claims 6 and 21, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of

resynchronization therapy, all in combination with the triggering condition being the number of consecutive intrinsic beats have exceeded a specified threshold value.

With respect to claims 7 and 22, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy, all in combination with the triggering condition being the number of times a pace has been inhibited by a synchronized-chamber protective period within a specified time interval has exceeded a specified limit value.

Regarding claims 8 and 23, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of

resynchronization therapy, all in combination with the triggering condition being the number of triggered paces in a specified time interval has exceeded a specified limit value.

With respect to claims 9 and 24, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy, all in combination with the controller being programmed to periodically measure the intrinsic PR interval by detecting the time interval between atrial and ventricular senses during unpaced beats, and wherein the triggering condition is when the measured PR interval has deviated a defined percentage from a previously measured intrinsic PR interval.

Regarding claims 10 and 25, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing

channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy, all in combination with the particular sensing channel from which data is to be stored and whether the data is to be stored as an electrogram or marker/interval data depends upon detection of a particular triggering condition.

With respect to claims 12 and 27, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy, all in combination with the triggering condition being when the delivered therapy is inconsistent with the programmed cardiac resynchronization therapy.

Regarding claims 33-34, the prior art of record fails to teach or suggest a cardiac rhythm management device with a controller which is programmed to pace both ventricles in accordance with a ventricular resynchronization pacing mode; and store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of resynchronization therapy or a method comprising outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode, storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating degradation of

resynchronization therapy, all in combination with the storage of data upon detection of a triggering condition is inhibited if a pathological condition is also detected.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Florio et al. (6,512,9530 shows a bi-ventricular pacemaker, which monitors capture and displays annotated electrograms. VanHout (6,668,194) shows triggering of a interventricular conduction time based on predetermined times of everyday, specified days of the week or month, or by a patient initiated measurement or some other programmed event.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Droesch

kld

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700